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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,567	09/04/2003	Futoshi Okada	Furuya Case 1407	6434

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FLYNN THIEL BOUTELL & TANIS, P.C.
2026 RAMBLING ROAD
KALAMAZOO, MI 49008-1631

EXAMINER	
KOSSON, ROSANNE	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/655,567	OKADA ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-19,24 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-19,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on January 17, 2006 has been received and entered. No claims have been amended. Claims 20-23 have been canceled. Claims 24 and 25 have been added. Accordingly, claims 16-19, 24 and 25 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, first paragraph

Upon reconsideration of the prior art, this rejection is withdrawn.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 recites a method of inhibiting the malignant progression of a benign tumor. A benign tumor does not progress malignantly, in the sense of malignant growth and spreading (i.e., metastasis). Thus, this claim language is confusing. If Applicants' intended meaning is that the change from benign to malignant is inhibited, the claim must be amended accordingly.

Claim Rejections - 35 USC § 103

Claims 16-19 are again rejected, and claim 24 is rejected, under 35 U.S.C. 103(a) as being unpatentable over Ginoux (U.S. 5,616,323) in view of Postaire et al. (U.S. 6,045,809), Takenaga et al. ("Effect of lecithinized superoxide dismutase (PC-SOD) on experimental pulmonary metastasis in mice," Free Radic Biol Med 26(9-10):1117-1125, 1999), van Rossen et al. ("Scavenging of reactive oxygen species leads to diminished peritoneal tumor recurrence," J Cancer Res 60:5625-5629, 2000) and Das et al. ("Inhibition of tumor growth and inflammation by consumption of tea," Phytother Res 16 (Suppl 1):S40-44, March 26, 2002). This rejection was discussed in the previous Office action.

Applicants assert that the claimed invention is not obvious because each of the cited references discloses a method of treating a malignant type of tumor to inhibit tumor growth or metastasis by administering SOD or gliadin-coated SOD (SOD-G). The references do not disclose a method of inhibiting the progression of a benign tumor to a malignant tumor.

In reply, what Applicants assert that have they done and what they assert not to be disclosed in the prior art is not what they have claimed. They have claimed a method of inhibiting the malignant progression of tumor, i.e., a method of inhibiting its growth or metastasis (see p. 8 of the specification, in particular, the last sentence). If Applicants wish to claim a method of inhibiting the progression of a benign tumor to a malignant tumor, i.e., its conversion or transformation, they should amend the claims accordingly.

As previously discussed, Ginoux et al. disclose administering SOD-containing extracts from melon to treat cancer (see column 1, lines 6-10 and 59-65, column 2, lines 21-24, and column 5, lines 13-29). Postaire et al. disclose a composition comprising superoxide dismutase (SOD) and gliadin, to stabilize this enzyme at acidic pH and provide a controlled release formulation that has improved bioavailability (absorption) compared to prior compositions (see column 3, lines 1-11). The plasma half-lives of uncoated SODs are very short (see col. 1, lines 37-39). van Rossen et al. disclose that intraperitoneal administration of SOD to mice inhibits the metastasis of tumors to various other organs in the abdominal cavity and decreases the size of the tumors (see Abstract; p. 5625, 3^{d} paragraph; p. 5626, last full paragraph; p. 5627, last full paragraph; and p. 5628, Table 2). Das et al. disclose that, when black or green tea extract is administered to mice intragastrically, serum levels of SOD increase, and this increased SOD activity inhibits the progression of a tumor (see p. S40, Abstract and last two paragraphs; p. S41, paragraph entitled Tumour Growth; p. S42, Fig. 2; and p. S43, 2^{d} and 3^{d} full paragraphs). Takenaga et al. disclose that, when lecithinized SOD is administered intravenously to mice, the metastasis of pulmonary tumors is inhibited by about 50% (see Abstract, p. 1119 and p. 1120, Fig. 1). Thus, the prior art clearly teaches that administering a therapeutically effective amount of SOD inhibits malignant tumor progression, as measured by a decrease in tumor size and rate of metastasis.

Regarding claim 24, which states that the tumor is a colon tumor, as noted by Applicants and in the prior art, SOD-G is formulated for oral administration. A pharmaceutical product that is taken orally contacts the tissues of the gastrointestinal

tract. Thus, one of ordinary skill in the art at the time that the invention was made would have expected that the SOD-G in a preparation that had been consumed orally would have contacted the tissues of the GI tract, including the colon, in a person or animal who had consumed the SOD-G preparation. Also, the cited art discloses that SOD can inhibit the progression of tumors in the lungs and in various organs in the abdominal cavity. The action of SOD is not organ-specific. As such, one of ordinary skill in the art would have reasonably expected SOD to inhibit the progression of colon tumors as well.

Regarding Applicants' Declaration under 37 CFR §1.132, one of the inventors has performed an experiment similar to that described in the specification with a different mouse model, using FPCK-1-1 cells (human, non-tumorigenic colon adenoma cells) instead of QR-32 cells. The results of the experiment show that nude mice treated with SOD-G developed fewer tumors, colon adenocarcinomas, following implantation of a plastic plate to which FPCK-1-1 cells were attached, compared to mice treated with no SOD or uncoated SOD. As the SOD was administered orally, the uncoated SOD may have been degraded before it had the opportunity to act therapeutically. Thus, no unexpected results with SOD-G vs. SOD are shown. As discussed above, the cited art teaches that SOD inhibits the malignant progression of tumors (growth and metastasis). Thus, the Declaration does not serve to overcome the rejections of record.

In view of the foregoing, the rejection of record is maintained.

Regarding claim 25, the prior art does not teach that treatment with SOD-G inhibits the conversion of benign tumor cells to malignant tumor cells.

No claim is allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner, Art Unit 1653

rk/2006-02-09

ROBERT A. WAX
PRIMARY EXAMINER